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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/683,828 | 02/20/2002 | Victor V. Gogolak | 597932000320 | 7476 |

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| EXAMINER | |
|---|---|
| RAYYAN, SUSAN F | |

| ART UNIT | PAPER NUMBER |
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| 2167 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/683,828 | GOGOLAK ET AL. | |
| | Examiner | Art Unit | |
| | SUSAN FOSTER RAYYAN | 2167 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *4/8/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 8, 2008 has been entered.

## DETAILED ACTION

2. Claims 1-2 ,4-17 are pending.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 6,507,829 issued to Jon Richards et al ("Richards") and US Patent Application Publication Number 2002/0010595) issued to Thomas L. Kapp ("Kapp") and further in view of US 6,188,988 B1 issued to David W. Barry et al ("Barry").

As per claim 1 Richards teaches:

creating a … syntax (col.9, lines 10-15);

detecting at least one instance of … content from a drug information source (col.4, lines 40-45,57-63);

and parsing … elements from at least one identified instance of ….content into the … rule syntax, retaining associations described in said drug rule content between drug rule elements that form a …, whereby a subset of the drug information source is processed into syntax-parsed … (col.5, lines 35-40, col.6, lines 20-29) .

Richards does not explicitly teach drug rule. Kapp does teach drug rule (paragraph 13, lines 1-5) to provide access current information about patient specific drugs (parag. 11, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Richard with a drug rule to provide access current information about patient specific drugs (parag. 11, lines 1-5).

Richards and Kapp do not explicitly teach comprising (a) drug rule syntax elements, each corresponding to a subset of a logical proposition, and (b) allowable logical relationships between said drug rule syntax elements. Barry does teach this limitation (at column 10, lines 35-52, as knowledge base may have subjective rules, objective rules and system generated rules. An example of an objective rule : if .... then reject the therapy). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Richards and Kapp with teach comprising (a) drug rule syntax elements, each

corresponding to a subset of a logical proposition, and (b) allowable logical relationships between said drug rule syntax elements to improve the treatment of a disease by providing guidance selection of a therapeutic treatment as described by Barry at abstract and column 6, lines 40-43.

As per claim 2, same as claim arguments above and Richards teaches:
wherein drug source information comprises at least one of: drug label information;
and drug literature information (col.2, lines 10-12).

As per claim 13 Richards teaches:
creating a … syntax (col.9, lines 10-15) ;
extracting metadata from the drug information source (col. 4, lines 40-45, 57-60 and col.5, lines 35-40 and col.6, lines 20-30);
extracting verbatim adverse event data from the drug information source (col. 4, lines 40-45, 57-60 and col.5, lines 35-40 and col.6, lines 20-30);
identifying at least one instance of drug rule content from the drug information source(col.4, lines 40-45,57-63);
; parsing …elements from at least one identified instance of …e content into the…syntax, retaining associations …. elements (col.5, lines 35-40, col.6, lines 20-29).

Richard does not explicitly teach drug rules, mapping terms from verbatim data to a reference source and wherein the drug described by the drug information source is characterized by the set comprising: the syntax-parsed drug rule elements, the mapped terms, and the metadata. Kapp does teach drug rules(paragraph 13, lines 1-5), mapping terms from verbatim data to a reference source (Figure 12, medication name, adverse events) and wherein the drug described by the drug information source is characterized by the set comprising: the syntax-parsed drug rule elements, the mapped terms, and the metadata (col.5, lines 35-40, col.6, lines 20-29) to provide access current information about patient specific drugs (parag. 11, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Richard with drug rules, mapping terms from verbatim data to a reference source and wherein the drug described by the drug information source is characterized by the set comprising: the syntax-parsed drug rule elements, the mapped terms, and the metadata to provide access current information about patient specific drugs (parag. 11, lines 1-5).

Richards and Kapp do not explicitly teach comprising (a) drug rule syntax elements, each corresponding to a subset of a logical proposition, and (b) allowable logical relationships between said drug rule syntax elements. Barry does teach this limitation (at column 10, lines 35-52, as knowledge base may have subjective rules, objective rules and system generated rules. An example of an objective rule : if .... then reject the therapy). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify

Richards and Kapp with teach comprising (a) drug rule syntax elements, each corresponding to a subset of a logical proposition, and (b) allowable logical relationships between said drug rule syntax elements to improve the treatment of a disease by providing guidance selection of a therapeutic treatment as described by Barry at abstract and column 6, lines 40-43.

As per claim 14, same as claim arguments above and Richard teaches:
wherein: the reference source comprises MedDRA (col.2, lines 10-12).

As per claim 15, same as claim arguments above and Kapp teaches:
wherein: the reference source is selectable by a user (Fig. 2 ref.no. 102-106).

As per claim 16, same as claim arguments above and Kapp teaches:
wherein: the mapping between a reference source term and the corresponding verbatim identifies the pedigree of each reference source term-verbatim pair (Figure 12, medication name, adverse events).

As per claim 17, same as claim arguments above and Kapp teaches:
associate remaining drug information source data with the drug, wherein the drug described by the drug information source is characterized by the set comprising: the syntax-parsed drug rule elements, the mapped terms, the metadata, and the remaining drug information source data (paragraph 13 and fig. 12) .

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Number 6,507,829 issued to Jon Richards et al ("Richards").

As per claim 4 Richards anticipates:

A computer-assisted method of processing a drug information source, the drug information source comprising at least one instance of adverse event content, each instance of adverse event content comprising at least one adverse event characterization (abstract) , the method comprising:

detecting at least one instance of adverse event content from a drug information source (col.4, lines 40-45, 57-60, extracting significant information from natural language text categorizing adverse event reports); and parsing at least one adverse event characterization from at least one detected instance of adverse event content (col.5, lines 35-40 and col.6, lines 20-29, verbatim are parsed) , whereby a subset of the drug information source is processed into at least one parsed adverse event characterization and wherein the at least one adverse

event characterization comprises quantitatively explicit information (col.6, lines 20-30, verbatim are parsed and weights are assigned sentence fragments of the to verbatim to allow extraction of significant information from the verbatim).

As per claim 5, same as claim arguments above and Richards anticipates: validating at least one parsed adverse event characterization (col. 9, lines 50-56).

As per claim 6, same as claim arguments above and Richards anticipates: wherein: adverse event content comprises text content, and each adverse event characterization comprises the set of reaction names and frequency of occurrence characterization (col.4, lines 40-45 and col.6, lines 20-27).

As per claim 7 same as claim arguments above and Richards anticipates: wherein: adverse event content comprises text content, and at least one adverse event characterization comprises the set of reaction names, lower limit frequency of occurrence, and higher limit frequency of occurrence(col.4, lines 40-45 and col.6, lines 20-27).

As per claim 8, same as claim arguments above and Richards anticipates: wherein: adverse event content comprises table content, and at least one adverse event characterization comprises the set of reaction names, and nominal frequency of occurrence (col.6, lines 20-27).

As per claim 9, same as claim arguments above and Richards anticipates:

wherein: adverse event content comprises table content, and at least one adverse event characterization comprises the set of reaction name, lower limit frequency of occurrence, and higher limit frequency of occurrence (col.6, lines 20-27).

As per claim 10, same as claim arguments above and Richards anticipates: wherein at least one instance of adverse event content comprises an implicit adverse event characterization, and the method further comprises deriving an adverse event characterization from the implicit adverse characterization (col.6, lies 36-40).

As per claim 11, same as claim arguments above and Richards anticipates: wherein: the derived adverse event characterization comprises the set of reaction names, and nominal frequency of occurrence (col.6, lines 20-27).

As per claim 12, same as claim arguments above and Richards anticipates: wherein: the derived adverse event characterization comprises the set of reaction names, lower limit frequency of occurrence, and higher limit frequency of occurrence(col.6, lines 20-27).

***Response to Arguments***

5. Applicant's arguments with respect to claims 1-2, 4-17 have been considered but are moot in view of the new ground(s) of rejection.

**Contact Information**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Rayyan whose telephone number is (571) 272-1675. The examiner can normally be reached M-F: 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Cottingham can be reached on (571) 272-7079. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Rayyan

June 14, 2008

/John R. Cottingham/

Supervisory Patent Examiner, Art Unit 2167